

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

(Study 2)

06/05/2009

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N0177: **A Pilot and Phase II Study of OSI-774 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme**

Study 2 (Mayo Rochester, Jacksonville, Scottsdale, University of Alabama at Birmingham, and University of Virginia only): **Prior to discussing protocol entry with the patient, call the Randomization Center (507/284-4130) for dose level and to insure that a place on the protocol is open to the patient.**

Registration date (date on) (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_

Patient study ID number (provided at time of Reg/Random) \_\_\_\_\_

NCCTG member (participant sponsor) \_\_\_\_\_

NCCTG treating location (chemo) \_\_\_\_\_  
(RT) \_\_\_\_\_

NCCTG treating physician (chemo) \_\_\_\_\_  
(RT) \_\_\_\_\_

Institution patient number (local subject number) \_\_\_\_\_

IRB approval date (chemo) (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_ IRB approval date (RT) (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_

Patient initials (last, first, middle) _____	Race (check all that apply)
Gender (check one) ___ Male ___ Female ___ Unknown	___ White
Date of birth (mm/dd/yyyy) ___/___/___	___ Black or African American
ZIP code _____	___ Native Hawaiian or Other Pacific Islander
Country of Residence _____	___ Asian
Method of payment (check one)	___ American Indian or Alaska Native
___ PI (Private Insurance)	___ Not reported: Patient refused or not available
___ MR (Medicare)	___ Unknown: Patient unsure
___ MRP (Medicare and Private Insurance)	Ethnicity (check one)
___ MD (Medicaid)	___ Not Hispanic or Latino
___ MM (Medicaid and Medicare)	___ Hispanic or Latino
___ MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	___ Not reported: Refused or data not available
___ MS (Military Sponsored [including CHAMPUS & TRCARE])	___ Unknown: Unsure of their ethnicity
___ MV (Veterans Sponsored)	
___ SP (Self pay [no insurance])	
___ NP (No means of payment [no insurance])	
___ OTH (Other)	
___ UNK (Unknown)	

Addendum 15 dated June 5, 2009 IRB approved?  
\_\_\_ Yes. If Yes, Addendum 15 approval date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_  
\_\_\_ No. If No, End form, Addendum 15 IRB approval required.

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Patient study ID number \_\_\_\_\_

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

\_\_\_\_

Currently on EIACs.

\_\_\_\_

Histologically confirmed glioblastoma multiforme (grade 4 of 4 astrocytoma). Gliosarcomas and other grade 4 astrocytoma variants (e.g., giant cell) may be included. Central pathology review is mandatory prior to study entry to confirm eligibility. It should be initiated as soon after surgery as possible.

\_\_\_\_

Patients must be enrolled  $\geq 1$  week after, but  $\leq 4$  weeks after biopsy or surgery.

\_\_\_\_

$\geq 18$  years. Age = \_\_\_\_\_. Because no dosing or adverse event data are currently available on the use of OSI-774 in patients  $< 18$  years of age, children are excluded from this study but will be eligible for future pediatric single-agent trials, if applicable.

\_\_\_\_

ECOG performance status  $\leq 2$  (Karnofsky  $\geq 60\%$ , see Appendix II).

**Which was done?**

\_\_\_\_

ECOG PS  $\rightarrow$  PS = \_\_\_\_\_.

\_\_\_\_

Karnofsky  $\rightarrow$  Karnofsky = \_\_\_\_\_.

\_\_\_\_

Life expectancy of  $\geq 6$  months.

\_\_\_\_

The following laboratory values obtained  $\leq 14$  days prior to registration. Earliest laboratory test date \_\_\_\_-\_\_\_\_-\_\_\_\_; latest laboratory test date \_\_\_\_-\_\_\_\_-\_\_\_\_. NOTE: These dates pertain to the following labs only.

\_\_\_\_

• ANC  $\geq 1500/\mu\text{L}$ . ANC = \_\_\_\_\_.

\_\_\_\_

• Hemoglobin  $\geq 9$ . Hemoglobin = \_\_\_\_\_.

\_\_\_\_

• PLT  $\geq 100,000/\mu\text{L}$ . PLT = \_\_\_\_\_.

\_\_\_\_

• Total bilirubin  $\leq$  institutional upper limit of normal (ULN)

Total bilirubin = \_\_\_\_\_; ULN = \_\_\_\_\_.

\_\_\_\_

• AST (SGOT)  $\leq 2.5$  x institutional (ULN). AST (SGOT) = \_\_\_\_\_; ULN = \_\_\_\_\_.

\_\_\_\_

• Creatinine  $\leq 1.5$  x institutional (ULN). Creatinine = \_\_\_\_\_; ULN = \_\_\_\_\_.

**Is this patient a woman of childbearing potential?** (This question may be answered yes or no.)

\_\_\_\_

Yes  $\rightarrow$  Complete; Negative serum pregnancy test ... question

\_\_\_\_

No  $\rightarrow$  Skip; Negative serum pregnancy test ... question..

\_\_\_\_

Negative serum pregnancy test done  $\leq 7$  days prior to registration, for women of childbearing potential only.

\_\_\_\_

Negative serum pregnancy test date \_\_\_\_-\_\_\_\_-\_\_\_\_.

\_\_\_\_

Ability to understand, and the willingness to sign a written informed consent.

**All responses in above section must be "Yes."**

\_\_\_\_

Any of the following because OSI-774 is an epidermal growth factor inhibitor with the potential for teratogenic or abortifacient effects based on the data suggesting that EGFR expression is important for normal organ development:

- Pregnant women
- Nursing women
- Men or women of childbearing potential who are unwilling to employ adequate contraception (condoms, diaphragm, birth control pills, injections, intrauterine device [IUD], surgical sterilization, abstinence, etc.)

\_\_\_\_

Other active cancers requiring therapy to control disease.

\_\_\_\_

Prior chemotherapy or radiation therapy for any brain tumor. No prior temozolomide.

\_\_\_\_

Receiving any other investigational agents.

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Patient study ID number \_\_\_\_\_

Eligibility Check - (Contraindications - continued)

Yes No

- \_\_\_\_ \_\_\_\_ Major surgery (excluding neurosurgical biopsy or resection of brain tumor) or significant traumatic injury occurring  $\leq 21$  days prior to treatment.  
Major surgery (excluding neurosurgical biopsy or resection of brain tumor) date \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable \_\_\_\_.  
Significant traumatic injury date \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable \_\_\_\_.  
Treatment start date \_\_\_\_ - \_\_\_\_ - \_\_\_\_.
- \_\_\_\_ \_\_\_\_ Abnormalities of the cornea based on history (e.g., dry eye syndrome, Sjogren's syndrome), congenital abnormality (e.g., Fuch's dystrophy), abnormal slit-lamp examination using a vital dye (e.g., fluorescein, Bengal-Rose), and/or an abnormal corneal sensitivity test (Schirmer test or similar tear production test).
- \_\_\_\_ \_\_\_\_ Gastrointestinal tract disease resulting in an inability to take oral medication or a requirement for IV alimentation, prior surgical procedures affecting absorption, or active uncontrolled peptic ulcer disease.
- \_\_\_\_ \_\_\_\_ Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.
- \_\_\_\_ \_\_\_\_ HIV-positive patients receiving combination anti-retroviral therapy are excluded from the study because of possible pharmacokinetic interactions with OSI-774. Appropriate studies will be undertaken in patients receiving combination anti-retroviral therapy when indicated.
- \_\_\_\_ \_\_\_\_ Receiving warfarin (Coumadin) therapy.
- \_\_\_\_ \_\_\_\_ Any history of allergy or intolerance to Dacarbazine (DTIC).

**All responses in above section must be "No."**

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

- \_\_\_\_ \_\_\_\_ Consent form signed and dated. Date informed consent signed \_\_\_\_ - \_\_\_\_ - \_\_\_\_.
- \_\_\_\_ \_\_\_\_ Authorization for use and disclosure of protected health information signed and dated.  
Date of authorization \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable (Non-U.S.A. institution only) \_\_\_\_.
- \_\_\_\_ \_\_\_\_ Treatment must commence and continue at an NCCTG institution under the supervision of a NCCTG member physician.
- \_\_\_\_ \_\_\_\_ Registration must be done  $\geq 1$  week but  $\leq 4$  weeks after biopsy or surgery.  
Date of surgery \_\_\_\_ - \_\_\_\_ - \_\_\_\_.
- \_\_\_\_ \_\_\_\_ Treatment cannot begin prior to registration and must begin  $\leq 7$  days after registration.
- \_\_\_\_ \_\_\_\_ Radiation oncology consult; Medical oncology consult; History; Toxicity assessment; Exam, wt, PS; Height; Neuro History and Exam; MMSE (Appendix V); Hematology group; Chemistry group; Serum free EIAC Level-(For patients taking EIAC [enzyme-inducing anticonvulsants] only); Anticonvulsant and steroid treatment log; sEGFR assay; and MGMT assay in blood must be completed  $\leq 14$  days prior to registration (see Section 4.0). Earliest pretreatment test date \_\_\_\_ - \_\_\_\_ - \_\_\_\_; latest pretreatment test date \_\_\_\_ - \_\_\_\_ - \_\_\_\_\_. NOTE: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date **and** the latest pretreatment test date must be greater than or equal to the latest laboratory test date.
- Exceptions to the above dates:**
- MRI or CT scan (MRI preferred but CT scans are accepted) up to 21 days before treatment (see Section 4.0).  
Date of MRI or CT scan \_\_\_\_ - \_\_\_\_ - \_\_\_\_.
- \_\_\_\_ \_\_\_\_ All required baseline symptoms must be documented and graded on the on-study form.
- \_\_\_\_ \_\_\_\_ Study drug availability checked.
- \_\_\_\_ \_\_\_\_ A radiation oncologist and medical oncologist have seen the patient and confirmed the patient is a suitable candidate for this study.

**All responses in above section must be "Yes."**

Patient study ID number \_\_\_\_\_

Registration Check – (continued)

Yes No

- \_\_\_\_ \_\_\_\_ Patients should be registered on NCCTG 94-72-52. Will this patient be registered on NCCTG 94-72-52? Randomization Center will register patients separately to the translational research component of this study (see Section 14.0). (This is optional.)
  - Patient has given permission to allow tissue samples to be used for the translational goals of this study
  - Patient has given permission to allow blood to be drawn and used for the translational goals of this study
- \_\_\_\_ \_\_\_\_ Patient has given permission to store blood sample(s) for future research of genetics.
- \_\_\_\_ \_\_\_\_ Patient has given permission to store tissue sample(s) for future research of genetics.
- \_\_\_\_ \_\_\_\_ Patient has given permission to store blood sample(s) for future research to learn, prevent, or treat other health problems.
- \_\_\_\_ \_\_\_\_ Patient has given permission to store tissue sample(s) for future research to learn, prevent, or treat other health problems.
- \_\_\_\_ \_\_\_\_ Patient has given NCCTG permission to give their blood sample(s) to outside researchers.
- \_\_\_\_ \_\_\_\_ Patient has given NCCTG permission to give their tissue sample(s) to outside researchers.

**Responses in above section may be “Yes” or “No.”**

Grouping Factor

Study  
2  
N/A 3

Descriptive Factors

- Family history of brain tumor
- \_\_\_\_ Yes (check all that apply)
- \_\_\_\_ Father
  - \_\_\_\_ Mother
  - \_\_\_\_ Brother or sister
  - \_\_\_\_ Child
  - \_\_\_\_ Other (list: \_\_\_\_\_)
- \_\_\_\_ No

- Contrast enhancement on preoperative scans
- \_\_\_\_ Yes
  - \_\_\_\_ No
  - \_\_\_\_ Uncertain

Maximum diameter in cm on a preoperative scan of:

Contrast Enhancement   .  (cm) vs. not applicable: \_\_\_\_

T2 abnormality on MRI or Low attenuation on CT   .  (cm)

- Corticosteroid therapy at study entry
- \_\_\_\_ Yes
  - \_\_\_\_ No

Assigned Treatment

**Study 2:**

- \_\_\_\_ E) RT + OSI-774\* + TMZ

\*OSI-774: Dose = \_\_\_\_\_ (mg); Level = \_\_\_\_\_  
RT: Dose is fixed at 6000 cGy

Person registering Signature \_\_\_\_\_ Registration Office specialist initials \_\_\_\_\_

Physician Signature \_\_\_\_\_ Date (mm/dd/yyyy) \_\_\_\_/\_\_\_\_/\_\_\_\_